

REMARKS

Applicants submit this Response to the Office Action dated May 26, 2010 and the Advisory Action dated September 21, 2010. In the Office Action, claims 1 to 15, 17 to 19 and 21 to 28 are pending and rejected, with claims 16 and 20 having been previously cancelled. By this Response, claims 1, 15, 18 and 24 have been amended. No new matter was added by these amendments. Support for these amendments is found at least at paragraphs [0108] and [0113] of U.S. Publication No. 2005/0065817. The Commissioner is hereby authorized to charge the Request for Continued Examination and any amounts deemed due to Deposit Account No. 02-1818.

In the Office Action: (a) claims 1 to 15, 17 to 19 and 21 to 28 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement; (b) claims 1 to 15, 17 to 19 and 21 to 28 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite; (c) claims 1 to 11, 13 to 15, 17 to 19, 21 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0038392 to De La Huerga ("*De La Huerga*") in view of U.S. Publication No. 2002/0093537 to Bocioned ("*Bocioned*") further in view of U.S. Publication No. 2003/0084024 to Christensen ("*Christensen*") in view of U.S. Patent No. 6,360,211 to Anderson ("*Anderson*") and further in view of U.S. Patent No. 5,953,706 to Patel ("*Patel*"); (d) claims 12 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over *De La Huerga* in view of *Christensen* and further in view of *Anderson* and U.S. Publication No. 2003/0105806 to Gayle et al. ("*Gayle*"); (e) claims 24, 25 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* in view of *Bocioned* and further in view of *Anderson* and *Patel*; (f) claims 26 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* and *Bocioned* in view of *Anderson*, *Patel* and *Gayle*; and (g) claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* in view of *Bocioned* and further in view of *Anderson* and *Patel*.

The rejection of claims 1 to 15, 17 to 19 and 21 to 28 under 35 U.S.C. §112 was indicated as having been overcome in the Advisory Action and is thus moot.

Regarding the rejection of claims 1 to 11, 13 to 15, 17 to 19, 21 and 23 under 35 U.S.C. §103(a) as being unpatentable over *De La Huerga* in view of *Bocioned* further in view of *Christensen* in view of *Anderson* and further in view of *Patel*, Applicants respectfully request that the rejection be withdrawn at least because: (i) one of ordinary skill in the art would not have

been motivated to combine the cited references and (ii) Applicants' claim amendments herein render the rejection moot.

I. One of Ordinary Skill in the Art would not have been Motivated to Combine Anderson, Patel and Christensen with the Other Cited References.

The Office Action relies on a combination of five references, three of which are not in the medical field, to allegedly arrive at the claimed invention. Applicants respectfully submit that the rejection is piecemeal and that one of ordinary skill in the art would not have been motivated to combine newly cited references *Anderson* and *Patel*, and *Christenson* with *De La Huerga* and *Bocioned*.

De La Huerga teaches a first central computer, a user interface, and a pump unit as part of one single "pump" 100. The Office Action also cites FIGS. 26A and 31 of *De La Huerga*, as evidence against the claims, asserting that element 622 serves as first central computer that communicates with a second computer 630. *Bocioned* is simply cited as a back-up to *De la Huerga* for its disclosure of a portable remote user interface which is connected to a server in communication with an intravenous pump. (See Office Action, page 7). *Christensen* is directed to a method and system of integrating databases for an **educational institution**. *Christensen* appears to have been cited merely to show a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database.

The Office Action concedes, as argued in Applicant's last Response, that *De La Huerga* does not disclose memory 622 being synchronized with data in memory of element 630 at designated time intervals, or critical information changing causing that information to be immediately relayed to communications device 620, citing *Anderson* and *Patel* to allegedly cure this deficiency.

Anderson is generally directed to a system and method for processing **invoice information** in which billing data is communicated from a first site to a second site. Page 8 of the Office Action asserts that *Anderson* discloses "synchronizing databases on a periodic basis" at column 7, lines 40 to 48:

Customer-specific information stored in intermediary database 66 is synchronized with the information stored in a corresponding customer database 86 on a periodic basis, e.g., on a daily basis. In

other words, new information stored in *customer database 86* is copied to intermediary database 66, and new information stored in intermediary database 66 is copied to *customer database 86*. Synchronization can be accomplished by any of several well-known methods. (Emphasis added).

Patel is generally directed to a *transportation network* system and method which integrates communications and data transmission requirements for ground transportation service providers into a single, centrally controlled network. Specifically, the network distributes reservations data and other travel-related information between ground service providers. Page 8 of the Office Action asserts that Anderson discloses “synchronizing databases immediately and automatically with any change in information at column 6, lines 55-63:

Any change in information communicated to the *TN system 1*, either from the New York site 3, the Los Angeles site 6, or an internal status update (e.g., from the OAG/RLM *flight information* database) is immediately and automatically communicated to various sites and all the databases at the various sites are synchronized with the identical information. (Emphasis added).

To rely on a reference under 35 U.S.C. §103(a), it must be analogous prior art. (See MPEP 2141.01(a)). “Under the correct analysis, any need or problem known in the *field of endeavor* at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007) (emphasis added). Thus a reference in a field different from that of applicant’s endeavor may only be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his or her invention as a whole.¹ *Christensen* is directed to a method and system of integrating databases for an educational institution, *Anderson* relates to a billing/invoicing network and *Patel* relates to a ground transportation network. None of these references are in the medical field (the field of endeavor of Applicants’ invention). One of ordinary skill in the art at the time of the invention evaluating the best way to accommodate validated and non-validated information in a medical information system would have had no reason to look to the above non-analogous references. Applicants’ field of endeavor is specific to an FDA-compliant medical system.

The separation of information in the claimed medical setting has inventive significance. As explained at paragraph [0108] of U.S. Publication No. 2005/0065817, “in one embodiment, a cost-effective integration of medical devices 120 or other devices and functionality with the hospital information systems in the first and second central computers 109, 108a is provided by isolating a subset of the total data mentioned above, such as patient safety-specific information, and locating such information and functionality in a validated/verified part of the system. In this context, *an FDA regulatory context*, verified means providing objective evidence that all requirements are tested and validated means providing objective evidence that the product meets customer needs.” (Emphasis added) By localizing a subset of the database, such as the *patient safety-specific data* at the first central computer, at least the cost of system development is further optimized, and integration with third-party non-validated systems and the respective data and information therein is made more time and cost effective. *Christensen, Anderson and Patel* have nothing to do with FDA-compliant validated/verified sub-systems, patient safety or the medical field in general.

II. Regardless, the Cited References Alone, or in Combination, do not Disclose Each and Every Element of the Amended Claims.

Claim 1, for example, has been amended to include the first central computer having a first database *including patient safety-specific information*, placing it even more firmly in the *medical* arena—unlike *Christensen, Anderson and Patel*, as discussed above. Claims 15, 18 and 24 have been similarly amended. Clearly, none of these non-analogous references teach or suggest the updating/synchronization of information regarding medical patient safety, being directed to billing, education and travel.

Claim 1 has also been amended to clarify that the second central computer has a second database, wherein the first database is a subset of the second database, and a second functional feature set, wherein the first central computer is securely connected to the second central computer, wherein the plurality of medical devices and the portable remote user interface do not communicate directly with the second central computer, the second central computer sending a signal to the first central computer at designated time intervals causing the subset of data in the first database to synchronize with the corresponding data in the second database, and when critical information in the second database changes which is also part of the first database,

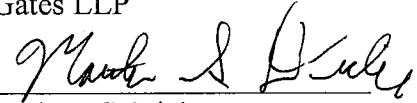
causing the information to be relayed immediately to and processed by the first central computer **and to be processed as a change in information, not as a replacement of existing information.** Claims 15, 18 and 24 have been similarly amended. This information is processed as a change of information for reasons specific to the medical art—the history of the patient must be logged. Such a system is much more complex than the simple synchronization systems cited the Office Action in different arts.

Anderson is generally directed to a system and method for processing **invoice information** and simply discloses new information being “copied to intermediary database 66.” (See *Anderson*, column 7, lines 40 to 48). *Patel* is generally directed to a **transportation network** system and method which integrates communications and data transmission requirements for ground transportation service providers into a single, centrally controlled network and simply discloses status information, such as flight information, being “communicated” and all databases being “synchronized with the identical information.” (See *Patel*, column 6, lines 55-63). Neither *Anderson* nor *Patel* make any distinction between information being processed as a change or simply replaced. For at least these and the above reasons, Applicants respectfully submit that claims 1 to 11, 13 to 15, 17 to 19, 21 and 23 are patentable over *De La Huerga*, *Bocioned*, *Christensen*, *Anderson* and *Patel* and in condition for allowance.

Regarding the rejection of claims 12 and 22 under 35 U.S.C. §103(a) as being unpatentable over *De La Huerga* in view of *Christensen*, *Anderson* and *Gayle*; claims 24, 25 and 27 under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* in view of *Bocioned* and further in view of *Anderson* and *Patel*; claims 26 and 28 under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* and *Bocioned* in view of *Anderson*, *Patel* and *Gayle*; and claim 27 under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* in view of *Bocioned* and further in view of *Anderson* and *Patel*, Applicants respectfully submit that the patentability of these claims flows from the patentability of the above-discussed independent claims.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. If the Examiner wishes to discuss the claims as amended herein or has any questions regarding this Response, Applicants encourage the Examiner to contact the undersigned by telephone.

Respectfully submitted,
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Dated: October 22, 2010